



EXHIBIT 1

Claims allowed in 275102080002
09/713,512

TECH CENTER 1600/2900

Clean copy of pending claims pursuant to 37 CFR 1.121(c)(3)

¹36. (Amended) A polyamine derivative, or salt thereof, wherein said derivative has the formula R_1-X-R_2 ,

wherein R_1-X- is of the formula $R-NH-CR'R''-CO-$,

wherein $-NH-CR'R''-CO-$ is a D- or L- form of valine, asparagine, or glutamine, or the D- form of lysine or arginine;

wherein R'' is H, CH_3 , CH_2CH_3 , or CHF_2 ;

wherein R is H or a head group selected from the group consisting of a straight or branched C_{1-10} aliphatic, alicyclic, single or multiring aromatic, single or multiring aryl substituted aliphatic, aliphatic-substituted single or multiring aromatic, a single or multiring heterocyclic, a single or multiring heterocyclic-substituted aliphatic and an aliphatic-substituted aromatic; and

wherein R_2 is a polyamine.

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²37. The derivative of claim ¹36 wherein R is H.

³38. The derivative of claim ²37 wherein $-NH-CR'R''-CO-$ is the D- form of lysine.

⁴39. The derivative of claim ³38 wherein R_2 is spermine.

⁵40. The derivative of claim ⁴39 wherein R_1-X- is attached to spermine at the N_1 position of spermine.

⁶41. A composition comprising a polyamine derivative or salt according to any one of claims ¹36-⁴39 and one or more pharmaceutically acceptable excipients.

⁷42. The composition of claim ⁶41 further comprising a polyamine synthesis inhibitor.

⁸43. The composition of claim ⁷42 wherein said inhibitor is difluoromethylornithine (DFMO).

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44. The composition of claim ⁶41 wherein said one or more pharmaceutical excipients are suitable for treating a disease or condition in which the inhibition of polyamine transport is desirable.

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45. The composition of claim ⁶41 further comprising one or more auxiliary agents or one or more liquid carriers.

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46. The composition of claim ¹⁰45 comprising a preservative or a stabilizer or both as said auxiliary agent.

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47. The composition of claim ¹¹46 comprising a stabilizer as an auxiliary agent.

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48. The composition of claim ¹⁰45 comprising peanut oil or olive oil as said liquid carrier.

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49. The composition of claim ¹⁰45 further comprising water.

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50. The composition of claim ⁶41 formulated as a solid.

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51. The composition of claim ¹⁵50 formulated as a capsule, impregnated wafer, tablet or powder.

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52. A method comprising contacting a cell with a polyamine derivative or salt according to any one of claims ¹⁷36-39.

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53. The method of claim ¹⁷52 wherein polyamine transport in said cell is inhibited.

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54. The method of claim ¹⁷52 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

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55. The method of claim ¹⁹54 wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neointima, tumor cells, or with undesired angiogenesis.

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56. The method of claim ²⁰55 wherein said disease or condition is cancer or post-angioplasty injury.

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57. The method of claim ¹⁹54 wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.

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58. The method of claim ¹⁹54 wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intranasally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.

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59. The method of claim ²³58 wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.

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60. (Amended) A method comprising contacting a cell with a polyamine derivative or salt thereof, wherein said derivative has the formula R_1-X-R_2 ,
wherein R_1-X- is of the formula $R-NH-CR'R''-CO-$,
wherein $-NH-CR'R''-CO-$ is the L- form of lysine or arginine;
wherein R'' is H, CH_3 , CH_2CH_3 , or CHF_2 ;
wherein R is H or a head group selected from the group consisting of a straight or branched C_{1-10} aliphatic, alicyclic, single or multiring aromatic, single or multiring aryl substituted aliphatic, aliphatic-substituted single or multiring aromatic, a single or multiring heterocyclic, a single or multiring heterocyclic-substituted aliphatic and an aliphatic-substituted aromatic; and R_2 is a polyamine
under conditions such that polyamine transport in said cell is inhibited.

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61. The method of claim ²⁵60 wherein R' and R are H; R₂ is spermine; and R₁-X- is attached to R₂ at the N₁ position of spermine.

^B
62. The method of claim 60 or 61 wherein polyamine transport in said cell is inhibited.

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63. The method of claim 60 or 61 wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

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64. The method of claim 63 wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neointima, tumor cells, or with undesired angiogenesis.

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65. The method of claim 64 wherein said disease or condition is cancer or post-angioplasty injury.

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66. The method of claim 63 wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.

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67. The method of claim 63 wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intranasally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.

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68. The method of claim 67 wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.

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69. A method comprising contacting a cell with a polyamine derivative or salt according to any one of claims ^{36 39}36-39 and a polyamine synthesis inhibitor.

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70. The method of claim 69 wherein said inhibitor is DFMO.

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71. ⁷³ The method of claim ~~69~~ wherein polyamine transport in said cell is inhibited.
- ³⁶
72. ⁷³ The method of claim ~~69~~ wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.
- ³⁷
73. ³⁶ The method of claim ~~72~~ wherein said undesired cell proliferation is associated with proliferation of cells of the immune system, cells of the vascular neointima, tumor cells, or with undesired angiogenesis.
- ³⁸
74. ³⁷ The method of claim ~~73~~ wherein said disease or condition is cancer or post-angioplasty injury.
- ³⁹
75. ³⁶ The method of claim ~~72~~ wherein said contacting is administration of said polyamine derivative or salt to said subject systemically or topically.
- ⁴⁰
76. ³⁶ The method of claim ~~72~~ wherein said contacting is administration of said polyamine derivative or salt to said subject orally, parenterally, transdermally, intravaginally, intranasally, intrabronchially, intracranially, intraocularly, intraaurally, rectally, by infusion, or by injection.
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77. ⁴⁰ The method of claim ~~76~~ wherein said administration by injection is intravenous, subcutaneous, intramuscular, intracranial, or intraperitoneal.
- ⁴²
88. ^{25 26} The method of claim ~~80~~ or ~~81~~, wherein said contacting further comprises contacting said cell with a polyamine synthesis inhibitor.
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89. ⁴² The method of claim ~~88~~, wherein said polyamine synthesis inhibitor is α -difluoromethylornithine.

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90. The method of claim ⁴²~~88~~ wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

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91. The method of claim ⁴³~~89~~ wherein said cell is in a subject with a disease or condition associated with undesired cell proliferation.

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92. The method of claim ⁴⁴~~90~~ wherein said undesired cell proliferation is associated with cancer.

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93. The method of claim ⁴⁵~~91~~ wherein said undesired cell proliferation is associated with cancer.

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94. The method of claim ¹⁹~~54~~ wherein said undesired cell proliferation is associated with cancer.

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95. The method of claim ²⁷~~63~~ wherein said undesired cell proliferation is associated with cancer.